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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,778	07/01/2002	Selim Aractingi	217365US0PCT	1465

22850 7590 09/26/2005

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/926,778

Applicant(s)

ARACTINGI ET AL.

Examiner

DiBrino Marianne

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 7/1/02 & 9/30/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-7 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

1. Applicant's amendments filed 7/1/02 and 9/30/02 are acknowledged and have been entered.
2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-3, drawn to a method of making a medicinal product comprising a composition essentially consisting of at least one soluble form of HLA-G and at least one pharmaceutically acceptable vehicle.

II. Claims 4-7, drawn to a method for preparing a soluble HLA-G comprising expressing soluble HLA-G in insect cells using baculovirus-expressed soluble HLA-G/ $\beta$ 2m and purifying the protein using an antibody generated against SEQ ID NO: 1.

3. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Independent claim 7 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by Fujii et al (J. Immunol. 1994, 153: 5516-5524) in view of Harlow and Lane (Antibodies: A Laboratory Manual, 1988, pages 72-79 and 93) as evidenced by admissions in the specification on page 8 at lines 18-25.

Fujii et al teach making antibodies to the unique 21 amino acid carboxyl-terminus on intron 4 of soluble HLA-G, and the resulting antibodies, and that they are useful in ELISA for detecting soluble HLA-G in maternal blood (especially page 5523 at the last paragraph and abstract and page 5517, column 1).

Fujii et al do not teach wherein the antibody is a rabbit or other non-human antibody made against SEQ ID NO: 1 coupled to KLH carrier protein.

Harlow and Lane teach making antibodies to carboxy-terminal peptides of proteins by coupling them to KLH carrier protein and injecting them into rabbits or other non-human animals (pages 72-79 and 93). Harlow and Lane further teach that a high percentage of antibodies generated against the carboxy-terminal sequences of proteins recognize the native protein (especially page 78 at the second to last paragraph).

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Admissions in the specification on page 8 at lines 18-25 are that SEQ ID NO: 1 is the C-terminal portion encoded by intron 4 of the soluble HLA-G forms.

It would have been obvious to one of ordinary skill in the art to have made a rabbit or other non-human antibody to the peptide that is a unique 21 amino acid carboxyl-terminus on intron 4 of soluble HLA-G taught by Fujii et al using the methodology taught by Harlow and Lane.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because Fujii et al teach and exemplify making antibodies to the said peptide, and Harlow and Lane teach the advantage of making antibodies to the carboxy terminal sequence of proteins, Fujii et al teach making antibodies to a unique 21 amino acid carboxyl-terminus peptide encoded by intron 4 of soluble HLA-G and that they are useful in detection assays, and the instant specification admits that the said C-terminal intron 4 peptide is SEQ ID NO: 1 of instant claim 7.

Therefore, because claim 7 does not provide a special technical feature, the instant invention lacks an inventive step and therefore lacks Unity of Invention.

4. **If Applicant elects Invention I**, Applicant is further required to (1) elect a single disclosed species (a **specific soluble HLA-G isoform(s)**, for example, HLA-G4) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

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8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

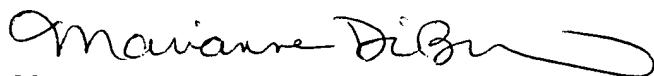
9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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September 15, 2005

  
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